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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/853,904 | 05/11/2001 | Scott J. Carter | VITLCOM.066A3 | 7612 |

33679 7590 01/24/2003

GE MEDICAL SYSTEM
C/O FOLEY & LARDNER
777 EAST WISCONSIN AVENUE
MILWAUKEE, WI 53202-5367

EXAMINER

OROPEZA, FRANCES P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3762

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,904

Applicant(s)

CARTER ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 4. 6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 2/11/02, Paper No. 2, notes a reference, "Prior art described in "Background of the Invention " section of present application", that has not been considered. Listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the Examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In claim 20, line 2 and claim 27, line 8, "the impedance" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 7, 9, 11-13, 16, 17, 21, 23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafner (US 5333617) in view of Hesen (US 3631851). Hafner substantially discloses the instant invention (figure 1; c 3, ll 4-15). The first input stage is read as the impedance detector (c 4, ll 44-62). The microprocessor (15) controls the final pacemaker stage and the final ECG stage, read to contain dynamic impedance matching circuits (c 3, l 47 – c 4, l 14; c 6, l 17 – c 7, l 17).

As to claims 3 and 17, the shields of the leads are the antenna (c 4, ll 23-29).

As to claims 9 and 23, the telemetry unit is a unidirectional transmitter unit (c 11, ll 28-32).

As to claims 5, 6, 19, 20 and 30, multiple antennas are disclosed (c 11, ll 32-36).

Hafner discloses the claimed invention except for a detachable lead set with a lead set connector.

Hesen teaches lead set attachment using a lead set connector (12) for the purpose of connecting multiple electrodes to a diagnostic electrocardiogram machine (c 2, ll 31-34). It would have been obvious to one having ordinary skill in the art at the time of the invention to

have used the lead set connector in the Hafner system in order to provide valid electrocardiogram signals with minimal noise so an accurate diagnosis is established (c 1, ll 8-24 and 54-58 and c 1, l 73 – c 2, l 4).

5. Claims 4, 8, 10, 18, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafner (US 5333617) in view of Hesen (US 3631851) and further in view of Flach et al. (US 5748103). As discussed in paragraph 4 of this action, modified Hafner discloses the claimed invention except for:

- the single-lead antenna being from a single lead (claims 4 and 18),
- the telemetry unit being an ambulatory telemetry unit (claim 8 and 22), and
- the telemetry unit being a transceiver unit (claims 10 and 24).

As related to the single-lead and the ambulatory unit, Flach et al. teach data transmission using a single-lead antenna to provide a light-weight design for the telemetry unit enabling patient ambulation so that the patient has freedom of movement while being monitored (c 5, l 66 – c 6, l 6). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the ambulatory telemetry unit with single-lead antenna in the modified Hafner system in order to permit patient mobility while collecting physiological data in a central location for review and response, as needed, by clinicians (c 1, ll 18-39).

As related to the transceiver, Flach et al. teach data transmission using a transceiver for the purpose enabling bi-directional communication between the telemetry unit and the central monitoring location. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the transceiver in the modified Hafner system in order to

enable the central location to use time slots to monitor and communicate with multiple telemetry units and to make control changes, as needed, in the telemetry units (c 3, ll 4-26).

6. Claims 5, 6, 19, 20 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafner (US 5333617) in view of Hesen (US 3631851) and further in view of Hafner (US 5333617). As discussed in paragraph 4 of this action, modified Hafner discloses the claimed invention except for the telemetry unit selecting the antenna from multiple potential antennas based in part on the output of the impedance detector.

Hafner teaches telemetry antenna selection using a central station and receiver (13) that selects between multiple antennas based in part on the output of the telemetry unit impedance detector for the purpose of using the strongest RF signal for data transmissions (c 11, ll 25-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the telemetry unit select the antenna from multiple potential antennas based in part on the output of the impedance detector, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

7. Claims 14, 15 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafner (US 5333617) in view of Hesen (US 3631851) and further in view of Unger et al. (US 5694940). As discussed in paragraph 4 of this action, modified Hafner discloses the claimed invention except for monitoring EEG, SpO2 and blood pressure data.

Unger et al. teach telemetric monitoring of physiological data using lead sets to transmit EEG, SpO2 and blood pressure data for the purpose of gathering and monitoring clinically significant data. It would have been obvious to one having ordinary skill in the art at the time of

the invention to have monitored EEG, SpO2 and blood pressure data in the modified Hafner system in order to collect and distribute significant physiological data signals so a patient's condition can be monitored (c 7, ll 9-14; c 1, ll 13-21; c 2, ll 20-26).

Other Prior Art Cited

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5231990 to Gauglitz teaches impedance detection circuitry.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JPO
1/19/03

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
1/21/03